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10/525,231	04/22/2005	Naresh Kumar	4137-44	7197
23117	7590	04/03/2008	EXAMINER	
NIXON & VANDERHYE, PC			GUDIBANDE, SATYANARAYAN R	
901 NORTH GLEBE ROAD, 11TH FLOOR			ART UNIT	PAPER NUMBER
ARLINGTON, VA 22203			1654	
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,231	Applicant(s) KUMAR, NARESH
	Examiner SATYANARAYANA R. GUDIBANDE	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 January 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 118-235 is/are pending in the application.
- 4a) Of the above claim(s) 118-141, 149-157 and 159-235 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 142-147 and 158 is/are rejected.
- 7) Claim(s) 148 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statements(s) (PTO/SB/08)
 Paper No(s)/Mail Date 1/17/08, 1/30/08, 2/15/08
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

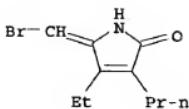
DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of group II invention and election of the following compound,



as the species in the reply filed on 8/24/07 is acknowledged. The traversal is on the ground(s) that the structure of the compounds of formula VI (group V) would not be burdensome to search when searching for the elected species and compounds of formula III (group II). Applicants request to include group V invention for examination on merit is appropriate. Accordingly, group II and group V inventions will be examined on the merit (claims 142-148 and 158) to the extent that they read on the formulae III and VI.

A search for the elected species indicated that it is free of prior art. The species recited in claim 148 have also been found to be free of art. The search was extended and art was found on the following compound,



that is used in the rejections as shown below.

Applicant's remarks and amendment to claims in the response filed on 1/17/08 has been acknowledged.

Claims 118-235 are pending.

Claims 118-141, 149-157 and 159-235 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 142-148 and 158 are examined on the merit.

Any objections and rejections made in the last office action dated 10/17/07 and not specifically mentioned here are considered withdrawn.

Allowable Subject Matter

Claim 148 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

Applicant's arguments, see pages 30-31, filed 1/17/08, with respect to the rejection(s) of claim(s) 146 and 158 under anticipation have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amendment to claims and newly found prior art.

Claim Rejections - 35 USC § 112, Second paragraph

Applicant's arguments, see page 33, filed 1/17/08, with respect to claims 142, 144 and 145 have been fully considered and are persuasive. The rejection of claims 142, 144 and 145 has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amendment to claims and new prior art found.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

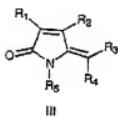
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 142-146 and 158 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as stated in the office action dated 10/17/07 and as reiterated in the modified form below. The rejection has been modified to reflect the amendments made to the instant claims. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Please note that applicant's arguments have been addressed at the end of the reiterated rejection.

In the instant application applicant's claim, formula III as shown below,



wherein, R1 and R2 are independently selected from H, halogen, substituted or unsubstituted alkyl, substituted or unsubstituted alkoxy, substituted or unsubstituted aryl, optionally interrupted by one or more hetero atoms,

R3 and R4 are independently selected from H, halogen, substituted or unsubstituted alkyl, substituted or unsubstituted alkoxy, substituted or unsubstituted aryl; and

R5 is selected from the group consisting of H, substituted or unsubstituted alkyl, substituted or unsubstituted aryl or substituted or unsubstituted arylalkyl, optionally interrupted by one or more hetero atoms.

The MPEP clearly states that the purpose of the written description is to ensure that the inventor had possession of invention as of the filing date of the application, of the subject matter later claimed by him. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v.*

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American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include, "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed invention is sufficient"

MPEP 2163.

The claim as recited encompasses innumerable compounds with variety of variables for each of the R1, R2, R3, R4 and R5 as recited in the claims. Each of the terms that define the variables in the claim is further expanded and defined to include any and all possible variations that define the term recited in the claim, for e.g., the term "alkyl" is further defined in the specification as "[T]he term "alkyl" is taken to mean both straight chain alkyl groups such as methyl, ethyl, propyl, isopropyl, butyl, isobutyl, sec-butyl, tertiary butyl, and the like. Preferably the alkyl group is a lower alkyl of 1 to 6 carbon atoms. The alkyl group may optionally be substituted by one or more groups selected from alkyl, cycloalkyl, alkenyl, alkynyl, halo, carboxyl, haloalkyl, haloalkynyl, hydroxy, substituted or unsubstituted alkoxy, alkenyloxy, haloalkoxy, haloalkenyloxy, nitro, amino, nitroalkyl, nitroalkenyl, nitroalkynyl, nitroheterocycl, alkylamino, dialkylamino, alkenylamine, alkynylamino, acyl, alkenoyl, alkynoyl, acylamino, diacylamino, acyloxy, alkylsulfonyloxy, heterocycl, heterocycloxy, heterocyclamino, haloheterocycl, alkylsulfenyl, alkylcarbonyloxy, alkylthio, acylthio,

phosphorus-containing groups such as phosphono and phosphinyl". Thus each of the other terms such as 'alkoxy', 'alkenyl', 'acyl', 'aryl', etc., are further defined on pages 24 and 25 of the specification. Thus, the claim as recited and the specification as disclosed encompasses multitude of compounds. However, the claim 148 recites structure of 9 compounds that correspond to formula III and specification discloses 8 compounds that correspond to formula VI. The number of compounds as recited in claims and disclosed in the specification is vastly inadequate to commensurate with the scope of the claims. There are no compounds either recited nor disclosed that corresponds to for e.g., R1, R2, R3 and R4 are substituted or unsubstituted aryl moiety, or substituted optionally interrupted by one or heteroatom, etc. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

Thus, the claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to applicant's arguments

Applicants argue that “[I]t is also believed that compounds of formula III or VI wherein R2 is aryl are taught by the disclosure of 5-hydroxy-5-methyl-4-phenyl-1,5-dihydropyrrol-2-one (first compound in the table on page 50) which is a compound of formula II. As described in the present application, compounds of formula III and subsequently compounds of formula VI may be synthesized from compounds of formula II. Further support for compounds of formula III and formula VI wherein R2 is aryl is provided by compounds 4f (page 13), 5e (page 16) and 6g (page 18) of PCT/AU01/00781 (incorporated by reference). A copies of pages 13, 16 and 18 of PCT/AU01/00781 are attached.

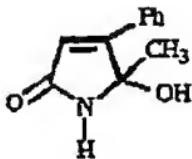
Using the same reasoning for R2 being aryl, it is clear that compounds of formula III or VI in which R3 and R4 are independently selected from aryl are supported by compound 70 (page 44 of PCT/AU01/01621 and page 39 of PCT/AU02/00797) which is a compound of formula I. Copies of pages 44 and 39 are attached. As described by the present application, compounds of formula II (and therefore compounds of formula III and subsequently compounds of formula VI) may be synthesized from compounds of formula I.

The definition of "alkoxy" for the variables R1-R4 has been limited to "C1-C10 alkoxy" in line with the definition at page 24. Compounds of formula III or VI in the specification in which R1, R2, R3 and R4 are alkoxy are supported by the disclosure of compound 85 of PCT/AU01/01621 (page 45) (copy attached) which is a compound of formula I".

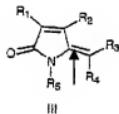
Applicant's arguments filed 1/17/08 have been fully considered but they are not persuasive. Applicants state that the “compounds of formula III or VI wherein R2 is aryl are taught by the disclosure of 5-hydroxy-5-methyl-4-phenyl-1,5-dihydropyrrol-2-one (first

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compound in the table on page 50)". This is not persuasive, the compound on page 50 is the compound represented by the following structure,



The above compound is not encompassed by the instant claims as there is no substituted double bond as required by compounds of formula III and VI as shown below with an arrow.



Further applicants argument that "R2 being aryl, it is clear that compounds of formula III or VI in which R3 and R4 are independently selected from aryl are supported by compound 70 (page 44 of PCT/AU01/01621 and page 39 of PCT/AU02/00797) which is a compound of formula I. Copies of pages 44 and 39 are attached" is not persuasive. The disclosed compounds shown in the evidence are all "furan" derivatives and instant claims are drawn to "pyrrole" derivatives.

Applicant's argument that, "[T]he definition of "alkoxy" for the variables R1-R4 has been limited to "C1-C10 alkoxy" in line with the definition at page 24. Compounds of formula III or

VI in the specification in which R1, R2, R3 and R4 are alkoxy are supported by the disclosure of compound 85 of PCT/AU01/01621 (page 45) (copy attached) which is a compound of formula I" is not persuasive. The disclosed compounds shown in the evidence are all "furan" derivatives and instant claims are drawn to "pyrrole" derivatives.

New grounds of rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 158 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 158 shows a variable 'Z' in the structure as shown in compound VI. However the claim as amended does not define the variable 'Z'. The chemical nature of 'Z' variable is unclear from the claim as recited and hence indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

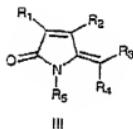
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 146, 147 and 158 are rejected under 35 U.S.C. 102(b) as being anticipated by

Mizutani, et al., 1998, J. Org. Chem., 63, 8769-8784.

In the instant application, applicants claim formula III as shown below,

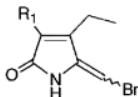


wherein, R1 and R2 are independently selected from H, halogen, substituted or unsubstituted alkyl, substituted or unsubstituted C₁-C₁₀ alkoxy, optionally interrupted by one or more hetero atoms,

R3 and R4 are independently selected from H, halogen, substituted or unsubstituted alkyl, substituted or unsubstituted C₁-C₁₀ alkoxy, substituted or unsubstituted aryl; and

R5 is selected from the group consisting of H, substituted or unsubstituted alkyl, substituted or unsubstituted aryl or substituted or unsubstituted arylalkyl, optionally interrupted by one or more hetero atoms.

Mizutani, et al., discloses a compound of the formula 13c (page 8770, scheme 1) shown below,



13b: R₁ = AcOCH₂CH₂

13c: R₁ = propyl

wherein, R1 is a propyl group, and R2 is ethyl groups and one of R3 or R4 is hydrogen or bromine, and R5 hydrogen atom as shown in the above figure that corresponds to the formula III of the instant application and hence meets the limitations of claim 146, 147 and 158. Since the Z of the formula VI of claim 158 is not defined in the claims as amended, the propyl group of the cited 13c compound meets the limitations of the claim 158.

Therefore, the cited reference of Mizutani anticipates instant invention.

Applicant's amendment to claims and newly found prior art necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654